

RULEMAKING ISSUE NOTATION VOTE

March 6, 2008

SECY-08-0031

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: PROPOSED RULE: EXPANSION OF NATIONAL SOURCE
TRACKING SYSTEM (RIN 3150-AI29)

PURPOSE:

The purpose of this paper is to request Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Parts 20 and 32 of Title 10 of the *Code of Federal Regulations*. The proposed amendments would expand the current National Source Tracking System (NSTS) to include additional licensees who possess sealed sources containing greater than or equal to 1/10th of International Atomic Energy Agency (IAEA) Category 3¹ threshold levels. The proposed rule would require these additional licensees to report transactions involving the manufacture, transfer, receipt, disassembly, or disposal of these nationally tracked sources. This paper does not address any new commitments.

SUMMARY:

In November 2006, the U.S. Nuclear Regulatory Commission (NRC) issued a final rule to establish a national system for tracking of certain sources. The rule requires licensees who possess IAEA Category 1 and 2 sources to report certain inventory and transaction information to the NSTS, currently scheduled to be launched in January, 2009. In proceeding with this current rulemaking, the staff has considered whether the existing NSTS should be expanded to

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¹ Sources referred to as "1/10th of Category 3" were formerly referred to as "Category 3.5" sources. To be consistent with IAEA terminology, the term "Category 3.5" has been changed to "1/10th of Category 3."

include Category 3 (or lower) sources to improve accountability and control over these sources and to reduce the potential for lower activity sources being accumulated (aggregated) to higher activity levels. Based on technical and policy considerations, and a regulatory analysis, the staff is requesting Commission approval to publish a proposed rule in the *Federal Register* that would amend 10 CFR Parts 20 and 32 to expand the NSTS to include sources greater than or equal to 1/10th of the IAEA Category 3 threshold.

BACKGROUND:

As a result of the September 11, 2001, attacks in the United States, NRC has undertaken a comprehensive review of nuclear material security requirements, with particular focus on risk-significant radioactive materials of concern. These materials have the potential to be misused in the absence of proper security measures. As part of this effort, the U.S. Government made a non-legally binding commitment to the IAEA Code of Conduct for safety and security of radioactive sources (henceforth referred to as the Code), which included a national registry of sources. Consequently, NRC issued a final rule in the *Federal Register* on November 8, 2006 (71 FR 65686), to establish a national system for source tracking. Under this program, licensees who possess IAEA Category 1 and 2 sources are required to report information on the manufacture, transfer, receipt, and disposal of nationally tracked sources. The implementation date for the NSTS has been extended to January 31, 2009.

In the 2006 rulemaking, the Commission specifically invited and received comments on whether Category 3 sources should be included in the NSTS (71 FR 65692). In response to the public comments received, the Commission noted that at that time it did not have adequate information to support inclusion of Category 3 sources in the NSTS; however it also noted that it was working to collect additional information by conducting a one-time survey of sources at a level of 1/10th of Category 3. It was also noted that a final determination on what additional sources should be included in the NSTS would be deferred to a subsequent rulemaking, which is the subject of this rulemaking.

During the process of preparing the final rule establishing the NSTS for Category 1 and 2 sources, the staff provided the Commission with options for expanding the NSTS to provide enhanced controls for IAEA Category 3 sources (SECY-06-0094, April 24, 2006). In response to that paper, the Commission, in a staff requirements memorandum (SRM) dated June 9, 2006, directed the staff to collect the additional information noted above. The Commission also requested that the staff prepare a proposed rule which would consider expanding the NSTS to include Category 3 sources. Subsequently, in response to recommendations made by the U. S. Government Accountability Office regarding security issues in NRC's materials program, the staff provided the Commission with an Action Plan (SECY-07-0147, August 25, 2007) which included, as Recommendation S-2b, an action item indicating that the scope of the rulemaking to expand the NSTS should also include sources equal to 1/10th of Category 3. On September 18, 2007, the Commission approved the staff's Action Plan in SRM-SECY-07-0147.

DISCUSSION:

The IAEA source categorization scheme² includes five categories that are based on the potential for sources to cause deterministic health effects to persons exposed to them. Sources

² RS-G-1.9 "Categorization of Radioactive Sources"

in Category 1 and 2 are considered to be the most “dangerous” because they can pose a high risk to human health if not managed safely and securely. Category 3 sources are less than the Category 2 threshold and the Category 3 threshold is equal to or greater than 1/10th of Category 2; the Category 4 threshold quantities are 1/100th of the Category 3 quantities. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled.

In the rulemaking establishing the NSTS for Category 1 and 2 sources, specific rationale was provided for establishing tracking and initial inventory requirements for start-up purposes of the NSTS for Category 1 and 2 sources. In that rulemaking, it was noted that the U.S. Department of Energy (DOE)/NRC analysis of potential health effects from use of sources in a Radiological Dispersal Device or a Radiological Exposure Device identified radionuclide “quantities of concern” to be in a range similar to the IAEA Category 2 threshold values. Therefore, to allow alignment between domestic and international efforts to increase safety and security of radioactive sources, NRC adopted the IAEA Category 2 values and used them as a threshold in its November 2006 rulemaking decision regarding sources requiring tracking and inventorying in a national source tracking system.

In preparing this proposed rule, the staff has determined that there is a need to enhance the tracking of lower activity sources to improve accountability of these sources and to provide additional protection against aggregation of these sources to higher activity levels (e.g. above the Category 2 threshold). At issue is the extent appropriate for expanding the NSTS beyond Category 2, i.e., should the NSTS be expanded to include IAEA Category 3 sources or should it be expanded even further to include sources that are 1/10th of the Category 3 threshold (which would actually be a subgroup of the high-end of activities in the Category 4 source range). The staff considered, separately, the issues associated with adding each of these categories as discussed in Items 1 and 2, below.

1. Expanding the NSTS to Include Category 3 Sources

The staff believes that there is a need to enhance the accountability of Category 3 sources through improved tracking of these sources. The IAEA’s Code contains basic principles that the IAEA believes are necessary for the safe and secure use of radioactive materials. In the Code, the IAEA defines Category 3 sources (as well as the Category 1 and 2 sources) as “dangerous sources,” i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. The Code does not require tracking of sources below the Category 2 threshold. However, within the Code’s framework, individual member states may choose to track smaller sources. On the basis of its inclusion in the Code, the staff believes it is reasonable to include these Category 3 sources in the NRC’s source tracking system.

In addition, there is a potential for aggregation of Category 3 sources to a Category 2 level. This is considered by the NRC to be a “quantity of concern.” Category 3 sources could be readily aggregated to Category 2 levels, as part of a concerted effort to do so, as they represent sources with activity levels that range from just below the Category 2 threshold down to 1/10th of the Category 2 threshold. Thus, sources at the high end of the range of activities in Category 3 can be at levels just below the threshold of a Category 2 source, meaning that it

could take only a few sources to aggregate to Category 2. Major categories of licensees who possess Category 3 sources include fixed industrial gauges, well-logging operations, and brachytherapy machines. Because these sources are thus relatively widespread in use and relatively broadly used in industry, there would be potential for aggregation of sufficient numbers of them to Category 2 levels. Adding these sources to the NSTS with its initial inventory for startup and tracking requirements will provide for increased accountability and control of these sources because there would be a near real-time knowledge of source whereabouts and an ability to confirm an individual licensee's account of their sources.

Adding Category 3 sources to the NSTS would result in increased burden to the NRC and to the licensed industry for implementation and maintenance of the expanded NSTS. In the Regulatory Analysis (Enclosure 2) for this rulemaking, the staff analyzed the additional costs and benefits of expanding the NSTS to Category 3 levels. The existing NSTS has approximately 1,300 NRC and Agreement State licensees. An expanded NSTS including Category 3 sources would add approximately 1,000 licensees. As estimated in the Regulatory Analysis, the resultant overall annual cost to the industry and to the NRC would be approximately doubled as a result of this expansion. However the Regulatory Analysis concluded that this additional burden would be reasonable to incur given the additional improvement in accountability and control of these sources, and resultant enhancement of NRC's ability to protect public health and safety.

In addition to burden on licensees, there could be burden on NRC's tracking system itself due to the addition of licensees. The Commission in its June 9, 2006, SRM specifically directed the staff to consider whether an expanded NSTS would impact the NRC's ability to monitor Category 1 and 2 sources. The staff does not expect that expansion of the NSTS will compromise the information technology (IT) aspects of the NSTS due to the capabilities incorporated into the NSTS software. Since the IT design and software are flexible and expandable, the NSTS can accommodate the anticipated number of licensees and sources and the corresponding tracking activities. Although additional effort will need to be expended to monitor an expanded NSTS, NRC should be able to continue to adequately monitor the expanded NSTS and identify possible aggregation of sources if those resources are provided.

As previously stated, the Commission has received public comment on the issue of including Category 3 sources in the NSTS. Briefly stated, there were commenters that supported inclusion of Category 3 sources in the NSTS for some of the same reasons noted above, whereas a larger number of commenters opposed the inclusion of Category 3 sources based on the relatively low risk they present compared to the perceived large increased burden of adding these sources to the NSTS. In further considering these comments during this current rulemaking, the staff believes that it has considered the concerns of the commenters, pro and con, and evaluated the additional burdens which the rule would impose, in reaching its decision to include Category 3 sources in the NSTS.

Based on the IAEA definition of Category 3 as "dangerous" and the potential for aggregation to Category 2 quantities of concern, the staff believes that the same information to be included in the NSTS for Category 1 and Category 2 sources is also needed for Category 3 sources. Expanding the scope of the NSTS would provide NRC with information regarding purchases/transactions of sufficient numbers of Category 3 sources that could be aggregated into the equivalent of Category 2 sources. Tracking specific transactions of Category 3 sources

enhances accountability and would detect situations where a licensee's aggregate sources would create larger (more dangerous) quantities.

2. Considerations of Expanding the NSTS to Include Sources at 1/10th of Category 3

The staff also gave consideration to expanding the NSTS to sources below the Category 3 threshold, specifically to include a subset of IAEA Category 4 sources that are in the high end of the Category 4 radioactivity range (i.e., at a level of 1/10th of the Category 3 threshold) because of the potential for them to be aggregated to Category 2.

A principal rationale for including sources at 1/10th of the Category 3 threshold is the potential that a sufficient number of these higher-activity Category 4 sources could be obtained and aggregated to create the equivalent of Category 2 sources. These "high-end" Category 4 sources can be at levels just below the threshold of a Category 3 source, which is about 1/10th of the threshold of a Category 2 source, meaning that it would require about 10-12 of these sources to aggregate to Category 2. These high-end Category 4 (1/10th of Category 3) sources are possessed by the same licensees noted above, namely those with fixed industrial gauges, well-logging operations, and brachytherapy machines, and, as noted above, are relatively widespread in use and relatively broadly used in industry, thus allowing for the potential for aggregation of sufficient numbers of them to Category 2 levels.

As noted above for Category 3 sources, the staff estimated the additional costs and benefits of expanding the NSTS to 1/10th of the Category 3 threshold. As noted in the Regulatory Analysis, an expanded NSTS to include 1/10th of Category 3 sources would add approximately 2,500 licensees with a resultant overall annual cost to the industry that would be approximately doubled again. The staff recognizes that there is likely to be an expansion of calls to the help desk to clarify NSTS reporting requirements. With regard to the burden on the NSTS software and NRC resources, the staff believes that the system can accommodate these additional sources and that application of appropriate resources would not result in the expanded NSTS diverting attention from the monitoring of higher-risk Category 1 and 2 sources.

Based on these considerations of the nature of the sources at 1/10th of Category 3, their potential to aggregate to Category 2, and the costs to the licensed industry and the NRC, the staff concluded, using information from the Regulatory Analysis, that the additional costs are reasonable to incur given the additional improvement in accountability and control of these sources. Thus, the staff concluded that it was appropriate to also include, in the NSTS, sources below the Category 3 threshold but greater than or equal to 1/10th of the Category 3 threshold.

Because the inclusion in the NSTS of these sources at a level of 1/10th of Category 3 has not been addressed in previous Commission rulemaking documents and because of the lower potential for aggregation than for the Category 3 sources, the staff suggests in the *Federal Register* Notice (FRN) that the NRC specifically invite comment on the inclusion of these sources at 1/10th of Category 3 in the NSTS and asks three specific questions in the FRN related to numbers of licensees, numbers and types of sources, and the nature of the transaction process, so as to better inform NRC's decision-making on the inclusion of sources greater than or equal to 1/10th of Category 3 in the NSTS.

3. Staff conclusion regarding expansion of the NSTS

Based on the discussion in Items 1 and 2, above, the staff has concluded that it is appropriate to expand the NSTS to include sources that are in Category 3 and that also are greater than or equal to 1/10th of the Category 3 threshold. Expanding the NSTS to all sources greater than or equal to 1/10th of Category 3 would use the same web-based system as for Category 1 and 2 sources, thereby providing NRC with information regarding transactions involving sufficient numbers of sources equal to or greater than 1/10th of Category 3 that could be aggregated into the equivalent of a Category 2 source. Tracking specific transactions of sources greater than or equal to 1/10th of Category 3, enhances accountability for more sources, and would detect situations where a licensee's aggregate sources would create larger (more dangerous) quantities. In addition, with an expanded NSTS, NRC can be alert to discrepancies between transaction reports of manufacturing and distribution licensees and of the persons to whom the shipment of sources is being made. Data from the NSTS could be used in conjunction with other data management systems to provide for better source accountability. Expanding the NSTS is part of a comprehensive radioactive source control program, as discussed in SECY-07-0147. Although neither the existing NSTS, nor an expanded NSTS, can ensure the physical protection of sources, they can aid in providing greater source accountability.

Based on the considerations noted above, the proposed rule would expand the existing NSTS by requiring licensees with sources greater than or equal to 1/10th of Category 3 to report information to the NSTS on the manufacture, transfer, receipt, disassembly, and disposal of specifically-licensed sources. The expanded NSTS would remain consistent with international obligations and consistent with recommendations in the IAEA Code of Conduct for development of a national register of radioactive sources.

The FRN for this proposed rule (Enclosure 1) contains specific information on the content of this expanded NSTS. Since the actions required for reporting by the additional licensees subject to the NSTS are the same as those for licensees currently within the scope of the NSTS, information in Enclosure 1 is based on the FRN for the final rule establishing the NSTS for IAEA Category 1 and 2 sources (71 FR 65686). The information in Enclosure 1 provides licensees new to the NSTS, i.e., those with sources greater than or equal to 1/10th of Category 3 with similar information as was provided in the FRN for the final rule establishing the NSTS for IAEA Category 1 and 2 sources.

The staff considered an alternate approach for this rulemaking which would be to simply require licensees with sources greater than or equal to either the Category 3 threshold or 1/10th of the Category 3 threshold to conduct and report inventories of the sources in their possession. However, this alternative would not provide the necessary knowledge of source transactions in a timely manner and, in addition, lack of transaction data from other licensees would not tend to lead to a cross-check for accurate reporting of inventories. In addition, there would still be significant costs incurred as a result of such a rule including the costs of setting up an account in the NSTS (including licensee credentialing); of conducting inventories; of marking serial numbers; of inspection; of preparing Agreement State regulations; and of NRC system monitoring, operation, and maintenance.

It should be noted that some Category 3 sources are contained in generally licensed devices. At the present time, generally licensed devices are exempt from the reporting requirements of

the NSTS. In this context, the staff has a separate proposed rulemaking in progress which would expressly change the requirements for generally licensed devices so that these sources would only be possessed by specific licensees, and thus subject to the reporting requirements of an expanded NSTS.

The staff has met with DOE staff to discuss this rulemaking on the expansion of the NSTS to 1/10th of Category 3. DOE staff views were helpful and were considered in the development of this proposed rule. DOE's approach for expanding the NSTS for sources under their jurisdiction is still under consideration and NRC staff plans to continue working with DOE to coordinate our approaches.

The proposed rule is consistent with NRC strategic objectives and performance goals. The proposed rule would continue to ensure the protection of public health and safety and the environment, as well as continue to ensure the secure use and management of radioactive materials. While the proposed rule would not change the physical protection requirements for nationally tracked sources, the proposed changes are part of a comprehensive radioactive source control program. The proposed expanded NSTS would provide greater source accountability. Information in the expanded NSTS will enable NRC to better risk-inform its inspection and programs for byproduct material licensees by helping NRC focus on those licensees that actually possess nationally tracked sources, thus making NRC actions more efficient and effective.

The rulemaking will be conducted in an open process. The proposed rule will be published in the *Federal Register* for a 75-day public comment period. The draft proposed rule was prepared with participation by Agreement State representatives and the draft proposed rule was provided to the Agreement States for preliminary review. It is anticipated that to assist licensees in implementing the requirements of an expanded NSTS that NRC would provide licensees with guidance similar to that done for the current NSTS regulation for IAEA Category 1 and 2 sources.

Agreement State Issues

A copy of the draft proposed rule FRN was provided to the Agreement States on December 17, 2007, so they could have an early opportunity for review.

Five Agreement States, Colorado, Iowa, Illinois, Washington, and Wisconsin provided comments on the draft FRN.

One State commented that there was an error on the draft table of Appendix E of 10 CFR Part 20. They noted that the Category 3 and 1/10th of Category 3 threshold levels were off by a factor of 10. The values listed were 1/100th of the of the threshold values not 1/10th and were corrected to be 1/10th of the threshold value. Three commenters commented on the effect that the rulemaking would have on generally licensed devices because the text of the rulemaking deals mainly with specifically licensed devices. This rulemaking applies to specifically licensed devices only; a separate rulemaking for generally licensed devices is currently in development. One commenter suggested that import licenses of Category 3 sources and 1/10th Category sources be extended if tracking at this level is determined to be necessary. In addition, they stated consideration should be given to clarify the intent of the transfer of sources for companies who have multiple licenses in different states. These

comments were considered and not added to this rulemaking at this time. One commenter agreed with the text of the rulemaking and provided suggestions on ways to ease the burden and make the process of entering data into the NSTS more effective and efficient. Two commenters stated that the NSTS is not yet up and running and the NRC is premature in promulgating this rule. Currently as it stands, the NRC expects that the NSTS will be fully functional by the time this rule goes into final publication, therefore, the Agency will keep the current schedule for this rulemaking. A commenter from the State of Colorado inquired if the Increased Controls requirements (typically Category 1 and 2) applied to this rulemaking. Increased Control requirements only apply to Category 3 and 1/10th of Category 3 sources if they are aggregated to Category 2 levels. One commenter stated that this rulemaking would add increased burden on their State and increase the number of sources tracked from 135 to 1,092. They also stated that 1/10th of Category 3 is inconsistent with the definition of a "dangerous source." However, the staff felt it was necessary to consider 1/10th of Category 3 source material in this rulemaking because of the issue of aggregation.

NRC staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." Staff has determined that the proposed rule is classified as Compatibility Category "B." The NRC program elements in this category are those that apply to activities that have direct and significant transboundary implications. An Agreement State should adopt program elements essentially identical to those of NRC. The Compatibility Category B is the Category that was assigned to the final rule for issuance of the NSTS for IAEA Category 1 and 2 sources.

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to Parts 20 and 32 of 10 CFR (Enclosure 1).
2. Note:
 - a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.
 - b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
 - c. That a Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).
 - d. That appropriate Congressional committees will be informed of this action.
 - e. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

- f. Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

RESOURCES:

To complete and implement the rulemaking, 1.5 full-time equivalent positions will be required. These resources are included in the current budget.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB no later than the date the proposed rule is forwarded to the *Federal Register* for publication.

/RA/

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Enclosures:

1. *Federal Register* Notice
2. Regulatory Analysis

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- 1. *Federal Register* Notice
- 2. Regulatory Analysis

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